IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION — MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

MEMORANDUM IN SUPPORT OF MYLAN DEFENDANTS' MOTION TO DISMISS COUNTS ONE, TWO AND THREE OF THE MASTER CONSOLIDATED COMPLAINT FOR INDIVIDUALS

I. INTRODUCTION

Mylan Defendants move the Court pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss the following counts of the Master Complaint for their failure to state claims upon which relief can be granted:

1. Plaintiffs' claim for failure-to-warn (Count One) should be dismissed against Mylan Defendants for two reasons. First, Plaintiffs have failed to allege facts sufficient to plausibly establish that Mylan Defendants, as distributors of Digitek®, knew or had reason to know of the existence of a manufacturing defect prior to the drug's recall. Second, because no instructions or warnings could have made Digitek® containing "inconsistent or excessive doses of Digoxin," safe for consumer use, Plaintiffs have failed to adequately allege the existence of a warning defect.

2. Plaintiffs' claims against Mylan Defendants for manufacturing defect (Count Two) and design defect (Count Three) should be dismissed because product distributors that did not participate in a product's design or manufacture cannot be held liable for defects in the product.

II. BACKGROUND

Plaintiffs bring these consolidated actions seeking damages for personal injuries allegedly suffered as a result of the use of the drug Digitek®. Digitek® was manufactured by Actavis Totowa LLC ("Actavis") and distributed, at different times, by Mylan Pharmaceuticals Inc. ("MPI"), Mylan Bertek Pharmaceuticals Inc. ("MBP"), and UDL Laboratories, Inc. ("UDL").[1] On April 25, 2008, Actavis issued a nationwide recall of all strengths of Digitek® due to a possibility that non-conforming tablets may have been commercially released. Shortly after the recall, plaintiffs filed lawsuits in state and federal courts throughout the country, claiming injuries from alleged exposure to defectively-manufactured Digitek®.

On August 13, 2008, the Judicial Panel on Multidistrict Litigation issued an order coordinating and centralizing the federal cases before this Court. Plaintiffs filed their Master Complaint on February 9, 2009, asserting various causes of action against the defendants, including failure-to-warn, defective design and defective manufacture.

III. ARGUMENT

A. Rule 12(b)(6) Standard.

When considering a motion to dismiss under Rule 12(b)(6), the court must determine if the complaint contains "enough facts to state a claim to relief that is *plausible* on its face." *Giarratano v. Johnson,* 521 F.3d 298, 302 (4th Cir. 2008), quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). While the court must generally "take the facts in the light most favorable to the plaintiff," it is not required to "accept the legal conclusions drawn from the facts," or "accept as true unwarranted inferences, unreasonable conclusions, or arguments." *Id.* (quoting *Eastern Shore Mkts., Inc. v. J.D. Assocs. Ltd. P'ship,* 213 F.3d 175, 180 (4th Cir. 2000)). A

[1]UDL began distributing Digitek® in 1999. MBP distributed Digitek® from 1999 to 2005 and MPI began distributing Digitek® in 2005. MI has never distributed Digitek®.

plaintiff must allege facts sufficient to support each element of his or her claim to relief; unsupported conclusory allegations are not enough to survive dismissal under 12(b)(6). *Bass v. E.I. DuPont Nemours & Co.*, 324 F.3d 761, 765-766 (4th Cir. 2003).

In its review of the complaint, the court can consider "documents quoted, relied upon, or incorporated by reference in the complaint" as well as "official public records" without converting defendants 12(b)(6) motion into a summary judgment. *Gasner v. County of Dinwiddie*, 162 F.R.D. 280, 282 (E.D. Va. 1995); *see also*, *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 127 S.Ct. 2499, 2509, 168 L.Ed.2d 179 (2007) (holding that a court, in deciding a 12(b)(6) motion, may consider a document that is incorporated by reference into the complaint).

B. Plaintiffs' Failure-to-Warn Claim (Count One) Should Be Dismissed for Failure to Allege Knowledge and Failure to Describe Warning Defect .

Plaintiffs' failure-to-warn claim should be dismissed because Plaintiffs have failed to allege facts that plausibly establish that Mylan Defendants, as distributors of Digitek®, knew or had reason to know of the existence of a manufacturing defect prior to the drug's recall. Mylan Defendants cannot be held liable for failure to warn unless they had active or constructive knowledge that Digitek® was defective. *E.g.*, *Towner v. Grand Trunk W. R.R. Co.*, 57 Fed. Appx. 232, 237 (6th Cir. 2003); *Varano v. Jabar*, 197 F.3d 1, 3-4 (1st Cir. 1999); *Rohrbaugh v. Owens-Corning Fiberglas Corp.*, 965 F.2d 844, 847 (10th Cir. 1992); *Brazzell v. United States*, 880 F.2d 84, 86-87 (8th Cir. 1989); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 426 (2nd Cir. 1969).

The Master Complaint is devoid of specific factual allegations regarding Mylan Defendants' knowledge of a manufacturing defect. Plaintiffs rely solely on the contents of FDA warning letters issued to Actavis in 2006 and 2007 to conclude—unreasonably—that Mylan

Defendants knew, or should have known, that Digitek® was defective. *See* Master Complaint, §§ 118–52. Plaintiffs cannot rely on allegations against "Defendants" collectively to support their claims against Mylan Defendants individually; this type of generic pleading falls short of alleging facts sufficient to establish a plausible right to recovery and fails to give reasonable notice to Mylan Defendants of the factual basis of the claims against them. *See, e.g.*, *Bryson v. Gonzales*, 534 F.3d 1282, 1288-90 (10th Cir. 2008) (finding that complaint failed to allege sufficient participation by defendant in the alleged wrongs to state a claim for relief and noting that collective allegations against "defendants" generically did not provide each individual with fair notice of the factual basis of the claims against him or her.). Without specific factual allegations plausibly establishing Mylan Defendants' knowledge of a defect, Plaintiffs' failure-to-warn claim fails as a matter of law and should be dismissed.

Even with sufficient allegations of knowledge, Plaintiffs' failure-to-warn claim would fail. Count One of the Master Complaint is an attempt by Plaintiffs to recast their manufacturing defect claim as a defective warnings claim. Plaintiffs allege that, in addition to being defectively manufactured, the recalled Digitek® was defective because its label did not warn consumers that it was defectively manufactured:

> At all times relevant to this Complaint, Digitek® (Digoxin) was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous…because the labeling, packaging, and warnings were insufficient to alert consumers, including Plaintiffs, of the dangerous risks and reactions associated with the recalled Digitek® (Digoxin), including but not limited to failure to warn that the amount of active ingredient was not consistent among Digitek® (Digoxin) tablets and the amount of active ingredient was inconsistent with the dose on the Digitek® (Digoxin) label.[2]

[2]Compare this description with that of the alleged manufacturing defect: "…the recalled Digitek® (Digoxin)…was defective because the amount of active ingredient was not consistent among Digitek® (Digoxin) tablets and the amount of active ingredient was inconsistent with the dose on the Digitek® (Digoxin) label."

Master Complaint at ¶ 57 (emphasis added). Circular reasoning aside, these allegations fail to describe a warning defect.

By definition, a warning defect is capable of being cured by the inclusion of additional or alternative instructions or warnings that render the product reasonably safe for consumers:

> A product…is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor…and the omission of the instructions or warnings renders the product not reasonably safe.

Restatement (Third) of Torts: Prod. Liab. § 2 (1998) (emphasis added). Plaintiffs have failed to adequately allege the existence of a warning defect because no instructions or warnings could have made Digitek® containing "inconsistent or excessive doses of Digoxin," safe for consumer use. Master Complaint at ¶ 52. Accordingly, Plaintiffs' failure-to-warn claim fails as a matter of law and should be dismissed.

C. Plaintiffs' Manufacturing and Design Defect Claims (Counts Two and Three) Should Be Dismissed Because Mylan Defendants Did Not Design or Manufacture Digitek®.

Plaintiffs' claims against Mylan Defendants for alleged manufacturing and design defects should be dismissed because Mylan Defendants neither designed nor manufactured Digitek®. Under state products liability laws, product distributors that did not participate in the design or manufacture of a product cannot be held liable for defects in that product. *Vandelune v. 4B Elevator Components Unlimited*, 148 F.3d 943, 947 (8th Cir. 1998) (dismissing suit against distributor of safety device because plaintiffs presented no evidence that distributor participated in the design and manufacture of the device); *Geboy v. TRL Inc.*, 159 F.3d 993, 1000 (7th Cir. 1998) (no imposition of liability for negligence on a party in chain of distribution that did not assemble, inspect, or use product); *Johnson v. Am. Leather Specialties Corp.*, 578 F. Supp. 2d 1154, 1178 (N.D. Iowa 2008) (holding that distributor and retailer of dog leash who did not

design or manufacture the product were immune from liability for design and manufacturing defect claims (citing Iowa Code §613.18(1)(a)); *Kladivo v. Sportsstuff, Inc.*, Civ. No. 06-4924, 2008 WL 4933951 at *3-4 (D. Minn. Sept. 2, 2008) (dismissing products liability action against product distributor who exercised no control over product's design or manufacture and had no knowledge of defect); *Alonso v. Maytag Corp.*, 356 F. Supp. 2d 757, 761 (S.D. Tex. 2005) (holding that a party who "merely distributes" a defective product cannot be held liable for defect); *Caterpillar, Inc. v. Usinor Industeel*, 393 F. Supp. 2d 659, 684 (N.D. Ill. 2005) (noting that non-manufacturing defendant in a product liability case may be dismissed if it had nothing to do with product's alleged defect); *Russell v. Makita U.S.A.*, Inc., No. Civ. A. 198CV2163RWS, 2000 WL 174908 at *1 (N.D. Ga. Jan 11, 2000) (dismissing design and manufacturing defect claims against saw distributor of because distributor did not participate in the saw's design or manufacture).

Plaintiffs are aware that Mylan Defendants did not participate in the design or manufacture of Digitek®. Though not always consistently pleaded, this awareness is reflected in a number of Plaintiffs' factual allegations, as well as in the publically-available documents Plaintiffs cite in support of the Master Complaint. Master Complaint at ¶¶ 6, 13; April 25, 2008 Recall Notice; August 15, 2006 Warning Letter; February 1, 2007 Revised Warning Letter.

In Paragraphs 6 and 13 of the Master Complaint, Plaintiffs describe the roles of the individual defendants with respect to Digitek®:

> Mylan Inc. was engaged in the business of marketing, promoting, selling and and/or distributing Digitek®…
>
> …
>
> Actavis Group, through it manufacturing division, Actavis Totowa, LLC, designed, researched, tested, and manufactured Digitek® (Digoxin). Mylan Pharmaceuticals, Inc. distributed Digitek® (Digoxin) through its affiliates Mylan Bertek Pharmaceuticals, Inc. and UDL Laboratories, Inc…."

Master Complaint at ¶¶ 6, 13 (emphasis added). These roles are corroborated by the April 25, 2008 Recall Notice, which is cited by Plaintiffs in Paragraph 38 of the Master Complaint:

> Actavis Totowa LLC notified healthcare professionals of a Class I nationwide recall of all strengths of Digitek…The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc under a "UDL" label.

Master Complaint ¶ 38 (emphasis added).

Because Plaintiffs do not and, indeed, cannot allege that Mylan Defendants designed or manufactured Digitek®, Counts Two and Three of the Master Complaint fail to state claims for design and manufacturing defects and should be dismissed.

IV. PRAYER

For the reasons stated above, Mylan Defendants respectfully request that this Court dismiss with prejudice Counts One, Two and Three of the Master Complaint for failure to state a claim upon which relief may be granted and grant such other relief as the Court may deem just and proper.

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CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2009, I electronically filed the foregoing "Memorandum in Support of Mylan Defendants' Motion to Dismiss Counts One, Two and Three of the Master Consolidated Complaint for Individuals" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

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